DOCKET NO.: DRPK-0003 **Application No.:** 10/616,247

Office Action Dated: January 3, 2006

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Original) A method providing long term pain management, the method comprising the steps of:

surgically implanting a catheter to create an infusion site, wherein a discharge portion of the catheter lies in a peripheral neural structure;

surgically implanting an implantable pump and reservoir in subcutaneous tissue, wherein a proximal end of the catheter, and the reservoir, are in communication with the pump; and

operating the pump to deliver a predetermined dosage of medication through the discharge portion of the catheter into the infusion site, whereby pain management is provided.

- 2. (Original) The method of claim 1, wherein the neural structure is a brachial plexus nerve complex.
- 3. (Original) The method of claim 2, wherein the catheter is implanted using an axillary approach.
- 4. (Original) The method of claim 2, wherein the catheter is implanted using a subclavian, interscalene or infractavicular approach.
- 5. (Original) The method of claim 2, wherein implanting the catheter comprises the steps of:

placing a bore needle in communication with a grounding wire of a nerve stimulator; inserting the bore needle within a facial sheath of the brachial plexus; stimulating the bore needle to verify adequate placement within the facial sheath; inserting an arterial line wire through the bore needle;

stimulating the arterial line to verify arterial line location adjacent to the brachial plexus; and

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advancing the catheter over the arterial line and removing the arterial line.

6. (Original) The method of claim 5, wherein implanting the pump and reservoir further comprises the steps of:

making a first incision in skin and subcutaneous tissue at an arterial line skin penetration location;

making a second incision, creating a subcutaneous pocket, and inserting the pump into the pocket;

creating a subcutaneous tunnel between the pocket and the first incision; and threading the catheter through the subcutaneous tunnel to the pocket and attaching the catheter to the pump.

- 7. (Original) The method of claim 5, wherein the bore needle has a conductive protrusion located at a base thereof and extending therefrom to create an angle therebetween to facilitate attachment to the grounding wire of the nerve stimulator.
- 8. (Original) The method of claim 1, wherein the neural structure is a gasserian ganglion, a nasociliary nerve, a long ciliary nerve, an anterior ethmoidal nerve, a subraorbital nerve, a supratrochlear nerve, a maxillary nerve, an infraorbital nerve, a sphenopalantine nerve, a mandibular nerve, an inferior alveolar nerve, a lingual nerve, an auriculotemporal nerve, a masseter nerve or a mental nerve.
- 9. (Original) The method of claim 1, wherein the neural structure is a cervical plexus, a greater occipital nerve, a lesser occipital nerve, a greater auricular nerve, a stellate ganglion or a glassopharyngeal nerve.
- 10. (Original) The method of claim 1, wherein the neural structure is a brachial plexus with the catheter implanted using an interscalene approach, a brachial plexus with the catheter implanted using a supraclavicular approach, a brachial plexus with the catheter implanted using an infraclavicular approach, a brachial plexus with the catheter implanted using an axillary approach, a radial nerve, a median nerve, an ulnar nerve or a digital nerve.

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11. (Original) The method of claim 1, wherein the neural structure is a splanchnic nerve, a thoracic sympathetic ganglion or an intercostal nerve.

12. (Original) The method of claim 1, wherein the neural structure is a lumbar

sympathetic ganglion, a celiac plexus, an ilioinguinal nerve, an iliohypogastric nerve or a

genitofemoral nerve.

13. (Original) The method of claim 1, wherein the neural structure is a sciatic

nerve, a femoral nerve, a lateral femoral cutaneous nerve, an obturator nerve, a common

peroneal nerve, a saphanous nerve, a tibial nerve, a deep peroneal nerve, a superficial

peroneal nerve, a superficial saphaneous nerve or a superficial sural nerve.

14. (Original) The method of claim 1, wherein the catheter is lined with a metal

strip conducive to electrical conduction.

15. (Original) The method of claim 14, wherein the metal strip is stimulated to

verify adequate catheter placement adjacent to the neural structure.

16. (Original) The method of claim 1, wherein the medication is selected from the

group consisting of bupivacaine, tetracaine and lidocaine.

17. (Original) The method of claim 1, wherein the medication is selected from the

group consisting of opiods, antispasmodics, alpha 2 agonists and local anesthetics.

18. (Original) The method of claim 1, wherein the neural structure is in a thoracic

region.

19. (Original) The method of claim 1, wherein the neural structure is an

intercostal, interpleural, or paravertebral nerve complex.

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20. (Original) The method of claim 19, wherein implanting the catheter comprises the steps of:

inserting a bore needle into skin and contacting a transverse process; walking the bore needle cephalad off a superior boarder of the transverse process; inserting the bore needle through a superior costotransverse ligament and into the paravertebral space; and

advancing the catheter through the bore needle and into the paravertebral space.

- 21. (Original) The method of claim 1, wherein the neural structure is peripheral to a central nervous system.
- 22. (Original) A closed system providing long term pain management, comprising:

a surgically implanted catheter having a discharge portion lying in a neural structure peripheral to a central nervous system; and

an implantable pump and reservoir located in subcutaneous tissue, wherein a proximal end of the catheter, and the reservoir, are in communication with the pump and the pump is operated to deliver a predetermined dosage of medication through the discharge portion of the catheter into the peripheral neural structure, thereby alleviating pain and providing pain management.

- 23. (Original) The system of claim 22, wherein the medication is one of an opioid, antispasmodic, alpha 2 agonist or local anesthetic.
- 24. (Original) The system of claim 22, wherein the medication is selected from the group consisting of an opioid, antispasmodic, alpha 2 agonist and a local anesthetic.
- 25. (Original) The system of claim 22, wherein the medication is a combination of tetracaine, clonidine and baclofen.

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26. (Original) The system of claim 25, wherein the predetermined dosage of medication is approximately between 10-25 mg/day of tetracaine, approximately between 50-100 mcg/day of clonidine, and approximately between 50-100 mcg/day of baclofen.

- 27. (Original) The system of claim 22, where the catheter has an embedded and electrically conductive material throughout the catheter length sufficient to enable electrical conduction, the material facilitating stimulation to verify a catheter distal end location adjacent to the neural structure.
- 28. (Original) A surgical needle for use in inserting a catheter, comprising: an electrically conductive shaft having a first end adapted to enter a facial sheath of a neural structure, a second end, wherein the shaft has an interior channel running longitudinally therethrough; and

an electrically conductive protrusion extending from the shaft to create a corner therebetween, the protrusion facilitating connection of the needle to a nerve stimulator.

- 29. (Original) The surgical needle of claim 28, wherein the protrusion is adapted to be operatively connected to a clip located at a distal end of a grounding wire of a nerve stimulator.
- 30. (new) The method of claim 1, wherein the catheter is implanted using a needle, the needle comprising:

an electrically conductive shaft having a first end adapted to enter a facial sheath of a neural structure, a second end, wherein the shaft has an interior channel running longitudinally therethrough; and

an electrically conductive protrusion extending from the shaft to create a corner therebetween, the protrusion facilitating connection of the needle to a nerve stimulator.

31. (new) The method of claim 30, wherein the protrusion of the needle is adapted to be operatively connected to a clip located at a distal end of a grounding wire of a nerve stimulator.